

INFORMATION Notice 2022-01: issued 03/01/2022

Overview

The Iowa Department of Public Health (IDPH) has recently amended Chapter 41 to align with the current changes in technology of X-ray machines for mammography and stereotactic breast biopsy and reflect the requirements of the quality control programs outlined by the unit manufacturers. Additional amendments align the Department's rules with the Food and Drug Administration (FDA) on certain requirements outlined in the Mammography Quality Standards Act (MQSA).

The IDPH has also amended Chapter 41 to include changes related to stereotactic breast biopsy continuing experience and education.

IDPH Rule Revisions

The IDPH has amended Iowa Administrative Code (IAC) Chapter 41 including but not limited to the following:

[641-41.6\(136C\) X-ray machines used for screening and diagnostic mammography](#)

1. 41.6(3) Mammography personnel
2. 41.6(5) Quality assurance program

[641-41.7\(136C\) X-ray machines used for stereotactically guided breast biopsy](#)

1. 41.7(3) Physicians
2. 41.7(5) Radiologic technologist

Explanation of Rule Revisions

641-41.6(136C) X-ray machines used for screening and diagnostic mammography

1. Mammography Personnel
 - a. The IDPH rules for personnel continuing qualifications, specifically continuing experience and education, for interpreting physicians and radiologic technologists have previously been more stringent than the FDA and required individuals to maintain continuing qualifications (experience and education) at all times while performing mammography.
 - b. The IDPH has amended the requirements on personnel continuing qualifications (experience and education) for interpreting physicians and radiologic technologists to align with the FDA. Mammography facilities will need to prove each individual meets the continuing requirements (experience and education) on the day of inspection.**
2. Quality assurance program
 - a. The amendments for a mammography facility's quality assurance program align with the current changes in technology of x-ray machines used for mammography and reflect the

requirements of the mammography unit's quality control manual, the reading workstation (RWS) quality control manual or the quality control program outlined by the accrediting body.

- b. Retake (repeat or reject) analysis program
 - i. The IDPH rules for the repeat or reject analysis previously required the analysis to be performed every 250 patients or quarterly, whichever came first. If more than 250 mammograms were performed in one week, weekly analysis was acceptable.
 - ii. **The IDPH has amended the rule by removing the requirement of performing the analysis at 250 patients if that came before the quarterly time period established by the facility's quality control program. Facilities should complete the repeat or reject analysis at a minimum of quarterly or at the frequency required as stated in the quality control manual the facility follows.**

641-41.7(136C) X-ray machines used for stereotactically guided breast biopsy

- 1. Physicians
 - a. Maintenance of proficiency (continuing experience)
 - i. The IDPH rules for physician continuing experience previously required the performance of at least 12 stereotactically guided breast biopsies per year.
 - ii. **The IDPH has amended the requirements for physician continuing experience to:**
 - 1. **Following the first anniversary in which the requirements of this subrule were met, completion of a total of 12 breast biopsy procedures must be met for each calendar year with at least 6 being stereotactic breast biopsies. The remaining 6 can be any combination of the following and demonstration of the chosen combination needs to be clearly documented:**
 - a. **Stereotactic breast biopsy procedures.**
 - b. **Stereotactic biopsy of a stereotactic training phantom with documentation of steps taken or a written report.**
 - c. **Stereotactic breast biopsy case review – must be documented to include a review of pre-biopsy mammographic exam, scout and stereotactic positioning, biopsy needle pre-fire and post-fire positioning and targeting, specimen radiograph images, post biopsy images and review of post biopsy pathology results.**
 - d. **Mammographic guided and/or stereotactic guided wire localization procedures.**
 - e. **Ultrasound guided breast biopsy procedures.**
 - f. **MRI guided breast biopsy procedures.**
 - b. Maintenance of CME requirements (continuing education)
 - i. The IDPH rules for physician continuing education previously required individuals to maintain continuing education requirements at all times within the prior 36 months.
 - ii. **The IDPH has amended the requirements on physician continuing education. Stereotactic facilities will need to prove each individual meets the continuing education requirements on the day of inspection.**

2. Radiologic technologists
 - a. The IDPH rules for radiologic technologist continuing experience previously required the performance of at least 12 stereotactically guided breast biopsies per year.
 - b. The IDPH has amended the requirements for radiologic technologist continuing experience to:**
 - i. **Following the first anniversary in which the requirements of this subrule were met, completion of a total of 12 breast biopsy procedures must be met for each calendar year with at least 6 being stereotactic breast biopsies. The remaining 6 can be any combination of the following and demonstration of the chosen combination needs to be clearly documented:**
 1. Stereotactic breast biopsy procedures.
 2. Stereotactic biopsy of a stereotactic training phantom with documentation of steps taken or a written report.
 3. Stereotactic breast biopsy case review – must be documented to include a review of pre-biopsy mammographic exam, scout and stereotactic positioning, biopsy needle pre-fire and post-fire positioning and targeting, specimen radiograph images, post biopsy images and review of post biopsy pathology results.
 4. Mammographic guided and/or stereotactic guided wire localization procedures.
 5. Ultrasound guided breast biopsy procedures.
 6. MRI guided breast biopsy procedures.
 - ii. **The IDPH has amended the requirements on radiologic technologist continuing education. Stereotactic facilities will need to prove each individual meets the continuing education requirements on the day of inspection.**
 - c. Maintenance of CME requirements (continuing education)
 - i. The IDPH rules for radiologic technologist continuing education previously required individuals to maintain continuing education requirements at all times within the prior 36 months.
 - ii. **The IDPH has amended the requirements on radiologic technologist continuing education. Stereotactic facilities will need to prove each individual meets the continuing education requirements on the day of inspection.**

The remainder of the mammography and stereotactic rules throughout *IAC Chapter 41* remain in place and facilities are encouraged to continually review their policies and procedures to ensure continued compliance with all rules. The chapters that relate to radiological health can be reviewed on the website. <https://idph.iowa.gov/radiological-health>

Questions

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